REMARKS

This communication is responsive to the Official Action of December 22, 2005. Claims 1, 5, 6 and 8 presently appear in this case. No claims have been allowed. The Official Action of December 22, 2005, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for the treatment of inflammatory arthritis in a human subject by orally administering IB-MECA or Cl-IB-MECA in a daily amount of less than about 70 μg/Kg.

The interview between Examiner Lewis and the undersigned attorney conducted on March 29, 2006, is hereby gratefully acknowledged. In this interview, it was pointed out that as long as applicant's claims were entitled to the effective filing date of the provisional application, the Baharav reference of record could be antedated by an appropriate "Katz" declaration. The issue discussed at the interview was appropriate language for amending claim 1, that would find support in both the present application and in the provisional application, and would still define the claims over the Jacobsen patent discussed in applicant's previous Amendment. The undersigned attorney proposed amending the effective amount to read "an amount which is less than about 70 μg/Kg." This language is supported in the priority document, as will be discussed below. Furthermore, even though it no longer specifies that this is the total daily

dose, it is still substantially at the bottom of the range disclosed by Jacobsen so that applicant's previous remarks with respect to Jacobsen would still be applicable *mutatis mutandis*. In the course of the interview, Examiner Lewis agreed that he would be receptive to the proposal if filed with an RCE.

Claim 28 has been rejected under 35 U.S.C. §102(b) as anticipated by Baharav 2002. Furthermore, claims 1, 5 and 8-14 have been rejected under 35 U.S.C. §103(e) as being unpatentable over Baharav in combination with Burkly, and claims 6 and 7 have been rejected as being unpatentable over Baharav in combination with Burkly and further in view of Jacobsen. These rejections are respectfully traversed.

The examiner states that the anticipation rejection is under 35 U.S.C. §102(b). However, 35 U.S.C. §102(b) requires that the printed publication be dated more than one year prior to the date of the application for patent in the United States. The present application was filed on November 19, 2003, claiming the benefit of provisional application no. 60/427,182, filed November 19, 2002. MPEP §2133, relating to 35 U.S.C. §102(b), states that the one-year time bar is measured from the U.S. filing date and references MPEP §706.02, regarding the effective U.S. filing date of an application. MPEP §706.02.V(D) states:

> If the application properly claims benefit under 35 U.S.C. §119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully

supported under the first paragraph of 35 U.S.C. §112 by the provisional application.

In order to ensure that all of the present claims are fully supported under the first paragraph of 35 U.S.C. §112 by the provisional application, the claims have now been amended somewhat. The provisional application, no. 60/427,182, does not have explicit support for the parameter "a total daily dose of about 114 μg/Kg." However, at page 6, line 25, the provisional application discloses a maximum dose of about 70 μg/Kg. The same parameter is supported in the present specification at page 7, line 24. All the rest of the claim, i.e., the use of IB-MECA or Cl-IB-MECA for the treatment of inflammatory arthritis in a human subject by oral administration of the drug, is fully supported in the provisional application (noting, for example, claims 1, 2 and 5 as originally filed in the provisional application). Support for the parameter of present claim 5 is found, for example, in claim 4 of the provisional application as originally filed.

Claim 6 has now been amended to specify only that the active agent is administered twice a day and to delete reference to any specific dosage. Support for the concept of twice daily administration may be found, for example, at page 9, line 24, of the provisional application.

In the present application, claim 7 has now been deleted as have claims 9-14 and 28. Furthermore, claim 8 has been amended to insert the subject matter as had previously appeared in claim 14, i.e., to specify that the effective

amount is a dose within the range of about 0.1 to 1.5 mg. This language is supported in the provisional application, for example, on page 9, line 19.

Accordingly, all of the present claims are supported both by the present specification and by the specification of the provisional application and are thus entitled to the effective filing date of November 19, 2002. Therefore, in view of the present amendment to the claims, it is now clear that the Baharav reference is not available as a reference under 35 U.S.C. §102(b).

Baharav is also unavailable as a reference under 35 U.S.C. §102(a). Baharav is an abstract presented at a Congress on Advances in Oncology and lists as authors the present inventor and four others, namely Ehud Baharav, Sara Bar-Yehuda, Felix Mor and Avraham Weinberger. However, the four authors other than the present inventor, Pnina Fishman, were properly named as authors but none contributed to the inventive concept of the present invention. Accordingly, the work described in the abstract is not that of "another" and 35 U.S.C. §102(a) is not applicable.

To establish these facts, attached hereto is a declaration of the present inventor, Dr. Pnina Fishman, explaining why the other four authors are included as authors despite the fact that they did not contribute to any inventive input.

As Baharav is not available as a reference under either 35 U.S.C. §102(a) or (b), it also cannot be available

as a reference under 35 U.S.C. §103; it must be available as a reference under one of the provisions of 35 U.S.C. §102 before it can be used in an obviousness rejection. Without Baharav, which is the primary reference, the obviousness rejections must fall. Reconsideration and withdrawal of all of the prior art rejections in this case, each of which rely on Baharav as a primary reference, are therefore respectfully urged.

It is submitted that all the claims now present in this case clearly define over the references of record and fully comply with U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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